assumed a constant change in utility occurs with a one unit change in BMI. However, recent studies demonstrate the magnitude of changes in utility scores may vary depending on: a) whether a patient is valuing weight loss or gain; b) whether a smaller or larger change in body weight is being evaluated; and c) baseline BMI. **CONCLUSIONS:** Various utility values associated with body weight using different methodologies have been published. Careful consideration should be given to determine the most appropriate utility values to use in cost utility analyses of T2DM therapies.

POB9

DEVELOPMENT OF A NEW QUESTIONNAIRE FOR IDENTIFING PREDICTIVE FACTORS INFLUENCING WEIGHT LOSS THERAPIES

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OBJECTIVES: To develop a multidimensional specific questionnaire of factors related to weight loss therapies proposed for the assessment of therapy success or failure. **METHODS:** Three focus groups of patients where debriefed and an expert panel gathered relevant issues and converted them into 54 items around 9 dimensions: Alimentary Habits, Expectations towards Therapy, Effort and Concern, Emotion, Confidence, Believes, Motivation towards Physical Exercise, Motivation towards Weight Loss, and Perceived Control. Comprehension and legibility were questioned in a pilot sample. A first item reduction was done to avoid redundancies and to establish content agreement. Item reduction was carried out in a sample of patients using factor analysis. Feasibility, reliability, content validity and factor validity were assessed. **RESULTS:** A panel of 11 practitioners and researchers, belonging to different health centers in the Community of Madrid gathered 3 samples: One sample of 8 chronic patients participating in 3 focus groups; a sample of 8 patients to assess feasibility; a sample of 121 patients for item reduction. A first conceptual reduction conveyed a 32 item version. After measurement in a representative sample a final 17 items form was accepted. Items were arranged around 6 dimensions: Impulsiveness, External Locus of Control, Internal Locus of Control, Emotiveness, Motivation towards Therapy and Exercise, and Personal Image. Overall Cronbach's a was 0.772 (ICC 95% confidence interval = 0.698–0.835). The 6 dimensions solution accounted for 71.2% of variance, with all eigenvalues above 1. **CONCLUSIONS:** The new questionnaire is a very short inventory of factors which might have screening properties in order to forecast the efficacy of weight loss therapies. Although further prospective research is being carried out in order to assess predictive validity, basic psychometric properties are good as a baseline model. Resulting dimensions are meaningful and well formed.

POB10

RIMONABANT IMPROVES HEALTH-RELATED QUALITY OF LIFE IN OVERWEIGHT/OBESE PATIENTS WITH TYPE 2 DIABETES: RIO-DIABETES STUDY

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OBJECTIVES: To evaluate the impact of the first selective cannabinoid type 1 (CB1) receptor blocker, rimonabant, developed for the management of cardiometabolic risk factors, on health related quality of life (HRQOL) in overweight/obese patients with type 2 diabetes. **METHODS:** A total of 1045 patients with type 2 diabetes were randomized in a double-blind trial and received either rimonabant 5 mg, 20 mg or placebo. Patients completed the Impact of Weight on Quality of Life-Lite (IWQOL-Lite), a validated 31-item questionnaire specifically designed for HRQOL assessment in obesity, and reported days missed from work at baseline and every 3-months up to 1 year. Analyses were performed on mean score changes from baseline to 1 year in the ITT population. Clinical meaningfulness was assessed using the Effect Size (ES) method, which is a measure of change over time that takes into account the variability within the sample at baseline. **RESULTS:** At 1 year, patients administered rimonabant 20 mg once daily (N = 339) reported significantly greater improvement ($p < 0.001$, and $p = 0.03$ for Work) in IWQOL-Lite total score and 3 out of 5 domains (Physical Function, Self-esteem and Work) than patients in the placebo group (N = 348) (no significant change in Sexual Life and Public Distress). These improvements were clinically meaningful (ES > 0.2). Also, there was a trend to fewer days missed from work reported by patients on rimonabant 20 mg (720 days) compared with those on placebo (1242 days) over the study period ($p = 0.2$ based on the number of patients with at least 1 day missed from work). **CONCLUSIONS:** HRQOL results showed both a statistically significant and clinically meaningful improvement in total score and also several domains (Physical Function, Self-esteem and Work) of the IWQOL-Lite questionnaire, with rimonabant versus placebo after a once daily administration of 20 mg rimonabant in this population of overweight/obese patients with diabetes.

PAIN

PPN1

INTRAVENOUS PARACETAMOL IN POSTOPERATIVE PAIN MANAGEMENT—SYSTEMATIC REVIEW AND META ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: To assess the efficacy of a new, ready-to-use intravenous paracetamol in postoperative pain management in comparison with placebo, oral paracetamol, propacetamol and other NSAIDs. **METHODS:** Electronic databases search (Medline—PubMED, EMBASE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Core Biomedical Collection), until March 2006, was conducted for randomised controlled trials on postoperative pain management with intravenous paracetamol in monotherapy or in combined treatment. Only full text articles published in peer-reviewed journals were accepted. Study results were combined in meta-analysis plots using RevMan, where appropriate. **RESULTS:** Six studies met the inclusion criteria: four compared intravenous paracetamol with placebo, one with oral paracetamol, two with propacetamol and one with metamizole. All studies were methodologically of high quality (average 4.83 points in Jadad scale). Treatment with intravenous paracetamol was significantly superior to placebo in pain relief, pain intensity difference, reduction of opioid consumption and patient treatment satisfaction (by 22% to 325%). Patients treated with intravenous paracetamol received less opioids than treated with oral paracetamol, whereas incidence of postoperative nausea and vomiting did not differ. No significant difference was obtained between intravenous paracetamol and propaceta-

mol considering pain relief, pain intensity difference, patient's global treatment satisfaction and between intravenous paracetamol and metamizole on pain scores and pain scores on coughing. Intravenous paracetamol had safety profile similar to placebo. Adults treated with intravenous paracetamol had 9 times lower risk of adverse events (RR = 0.11; 95%CI: 0.05–0.24) and 30 times lower risk of infusion site reactions (RR = 0.03; 95%CI: 0.01–0.16), comparing with propacetamol. **CONCLUSIONS:** Intravenous paracetamol is an effective drug in postoperative pain management in children and adults as superior to oral paracetamol and placebo. Its efficacy is comparable to propacetamol and metamizole, with better safety profile.

PPN2

META-ANALYSIS OF DULOXETINE VS. PREGABALIN AND GABAPENTIN IN THE TREATMENT OF PERIPHERAL DIABETIC NEUROPATHIC PAIN

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OBJECTIVE: To compare the efficacy and tolerability of duloxetine (DLX) with pregabalin (PGB) and gabapentin (GBP) for the treatment of diabetic peripheral neuropathic pain (DPNP). **METHODS:** We searched PubMed, Ovid, CENTRAL databases and regulatory websites for randomized, double-blind, placebo-controlled, parallel group or crossover clinical trials (RCTs) assessing DLX, PGB and GBP in DPNP. Study arms using approved dosages with assessments after 5–13 weeks were eligible. Efficacy criteria were: reduction in 24-hour pain severity (24hPS) for all three drugs, and response rate (>50% pain reduction) and Patient's Global Impression of Improvement/Change (PGI-I/C) for DLX and PGB only. Tolerability criteria were: discontinuation, diarrhoea, dizziness, headache, nausea and somnolence. Pooled fixed- and random-effects analyses were conducted on endpoints reported in at least two studies of each drug. Each drug was compared with placebo. DLX was compared indirectly with PGB and GBP by meta-regression. **RESULTS:** Three studies of DLX, 6 of PGB and 2 of GBP were eligible. Between-study heterogeneity was insignificant. In random-effects and fixed-effects analyses, all drugs were superior to placebo for all efficacy parameters, with some tolerability trade-offs. Indirect comparison of DLX with PGB found no differences in 24hPS, but significant differences in PGI-I/C, favouring PGB, and dizziness, favouring DLX were apparent. Comparing DLX and GBP, there were no statistically significant differences. **CONCLUSIONS:** From the few studies available for indirect comparison, DLX shows comparable efficacy and tolerability to GBP and PGB in DPNP. Duloxetine provides an important treatment option for this disabling condition.

PPN3

SAFETY OF INTRAVENOUS FORMULATIONS OF METAMIZOLE, KETOPROFEN AND PARACETAMOL—ANALYSIS OF DATA FROM WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

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OBJECTIVES: Comparison of safety of intravenous metamizole, ketoprofen and paracetamol based on data from WHO Programme for International Drug Monitoring. **METHODS:** The data from countries participating in the World Health Organization Programme for International Drug Monitoring are collected and maintained, on behalf of the WHO, by the Uppsala Monitoring Centre, in the Vigibase. An analysis of data on adverse events (AE) of intravenous formulations of metamizole, ketoprofen and paracetamol, reported to Vigibase, from European countries since 1968 up to 29th January 2006 (ref: ER 132/2005), was performed. **RESULTS:** One thousand three hundred seventy one individual case reports of metamizole adverse events were registered in the Vigibase, compared to 367 and 69 for ketoprofen and paracetamol, respectively. Serious AE were reported in 29 metamizole cases, 47—ketoprofen and none for paracetamol. There were 15 death cases registered for metamizole, 1 for ketoprofen and paracetamol. Hematologic disorders were reported in 187 metamizole cases, i.e. 6 and 31 times more common then for ketoprofen and paracetamol therapy, respectively. Most frequent AE reports for metamizole were: anaphylactic shock (79 cases versus 6 and 3 with ketoprofen and paracetamol, respectively), agranulocytosis (77 vs 3 vs 1), rash erythematous (63 vs 26 vs 3), hypotension (54 vs 6 vs 3), pruritus (53 vs 10 vs 1), rash (51 vs 17 vs 0), leucopenia (48 vs 6 vs 2) and circulatory failure (48 vs 5 vs 2). **CONCLUSIONS:** Intravenous therapy with paracetamol is safer than with ketoprofen or metamizole, concerning total number of reported adverse events, number of reported serious adverse events and number of hematologic disorders. Death cases were reported 15 times more often with metamizole than with either paracetamol or ketoprofen.

PPN4

ECONOMIC EVALUATION COMPARING BMP-2 (INDUCTOSTM) VERSUS CURRENT TREATMENT IN CHRONIC LOWER BACK PAIN IN THE SPANISH SETTING

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Chronic lower back pain (CLBP) is a major economic burden on individuals, health care system and society as a whole. Spinal fusion surgery is recommended in patients with persistent pain. Most lumbar spinal fusion surgery involves the use of bone autograft from patient's iliac crest, which implies increased co-morbidity. InductOs® is indicated for single-level (L4–S1) anterior lumbar spine fusion as a substitute for autogenous bone graft in adults with degenerative disc disease (DDD). **OBJECTIVE:** To evaluate the potential economic benefits of InductOs® compared to autograft, in spinal fusions in patients with DDD in Spain. **METHODS:** An analytic decision tree model was developed in order to simulate the clinical pathways of a cohort of 1000 simulated patients with DDD. The analysis was performed from the perspective Spanish National Health System (payer), with a time horizon of 2 years. Clinical and economical data were retrieved from published studies and official tariffs, validated by a clinician trained in the management of these patients in the Spanish setting. **RESULTS:** In Spain, the use of InductOs® leads to a reduction in operation times and length of stay resulting in savings of €930 per patient, to a reduction of revisional spinal procedures resulting in further savings of €428 per patient, and to a faster return to work by an average of 54 days, resulting in additional savings of €2304 per patient from sickness-leave payments avoided. These savings offset the upfront cost of InductOs® of 2799 resulting in net cost savings of €863 per case treated, as compared to standard care. **CONCLUSION:** Adding